

UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

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In re Pharmaceutical Industry	)	
Average Wholesale Price	)	
Litigation	)	MDL No. 1456
	)	Master File No. 01-12257-PBS
This document relates to:	)	
UNITED STATES OF AMERICA	)	
ex rel. VEN-A-CARE OF THE	)	
FLORIDA KEYS, INC.	)	
	)	
Plaintiff,	)	
	)	
v.	)	
	)	
BOEHRINGER INGELHEIM	)	
CORPORATION, et al.	)	
	)	
Defendants.	)	
	)	
CIVIL ACTION NO. 07-10248-PBS	)	
	)	

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**MEMORANDUM AND ORDER**

December 6, 2007

Saris, U.S.D.J.

**INTRODUCTION**

The United States brings this action under the False Claims Act ("FCA"), 31 U.S.C. §§ 3729-3733 and state law,<sup>1</sup> seeking to

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<sup>1</sup> The government's complaint-in-intervention states four causes of action against Roxane. Count 1 alleges that Roxane violated the False Claims Act, 31 U.S.C. § 3729(a)(1), by presenting or causing to be presented a false claim to the federal government. In addition, Count 1 asserts that Roxane contravened the FCA by violating the Anti-Kickback Statute. Count 2 alleges that Roxane violated 31 U.S.C. § 3729(a)(2) by making or using false records and statements to cause claims to be paid. Count 3 alleges a cause of action for unjust enrichment. Count 4 alleges a claim for common law fraud.

recover losses to the Medicare and Medicaid programs caused by allegedly excessive and fraudulent Average Wholesale Prices ("AWPs") and Wholesale Acquisition Costs ("WACs") for certain drugs, reported by defendants Boehringer Ingelheim Corporation, Boehringer Ingelheim Pharmaceuticals, Inc., Boehringer Ingelheim Roxane, Inc., and Roxane Laboratories, Inc. (collectively "Roxane").<sup>2</sup> The alleged fraudulent AWP pricing scheme began by 1996 and continued to 2004 in the case of the Medicare program and continues to the present in the case of the Medicaid program. (Compl. ¶ 58.)

Roxane has moved to dismiss the complaint of the United States and the complaint of relator Ven-a-Care of the Florida Keys, Inc. (hereafter, "Ven-A-Care"). Among other things, Roxane argues that the claims are largely time-barred by the six year statute of limitations set forth in 31 U.S.C. § 3731(b)(1). Citing United States v. Baylor Univ. Med. Ctr., 469 F.3d 263 (2d Cir. 2006), Roxane contends that the action is deemed to have been commenced against Roxane for statute of limitations purposes when the complaint in intervention was filed by the government on February 9, 2007 and that any false claims submitted prior to February 9, 2001 (six years earlier) are time-barred.

After hearing, the Court **ALLOWS**, in part, and **DENIES**, in part, Roxane's motions to dismiss.

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<sup>2</sup>The United States contends that defendants functioned as "one single entity." (Compl. ¶ 19.)

**PROCEDURAL HISTORY**<sup>3</sup>

On April 10, 2000, Ven-A-Care filed a sealed *qui tam* complaint in the District of Massachusetts against several defendants, including Roxane Laboratories, Inc. ("Roxane").<sup>4</sup> Ven-A-Care alleged that Roxane falsely represented the wholesale prices for certain of its generic drugs in order to cause state Medicaid programs to pay excessive reimbursements. Ven-A-Care also represented that it provided information about Roxane's purported conduct to the federal government "on or before November 1996." (Ven-A-Care Compl. ¶ 8.)

Roxane received a subpoena from the government for documents regarding the pricing of Ipratropium Bromide within months of the relator's having filed suit as part of the government's investigation. In addition, Roxane was sued by the State of Texas in 2000 on similar allegations.

Ven-A-Care amended its April 2000 Massachusetts *qui tam*

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<sup>3</sup>The factual basis for the alleged fraudulent pricing scheme is set forth in this Court's prior opinions in California ex rel. Ven-A-Care of the Fla. Keys, Inc. v. Abbott Labs., Inc., 478 F. Supp. 2d 164 (D. Mass. 2007); United States ex rel. Ven-A-Care of the Fla. Keys, Inc. v. Abbott Labs., Inc., 491 F. Supp. 2d 12 (D. Mass. 2007) with which the Court assumes familiarity. This Court also assumes familiarity with the legal issues presented in United States ex rel. Ven-A-Care of the Fla. Keys, Inc. v. Dey, Inc., 498 F. Supp. 2d 389 (D. Mass. 2007), many of which overlap with the Roxane defendants' motions to dismiss.

<sup>4</sup>In 1995, Ven-A-Care filed a *qui tam* complaint in the Southern District of Florida but Roxane was not named as a defendant.

complaint on three occasions: on February 15, 2001, February 1, 2002, and February 15, 2005. The first complaint alleged wrongdoing with respect to one drug, Ipratropium Bromide, and one Roxane entity. In the third amended complaint, relators alleged claims based on numerous drugs against multiple defendants, including the four Roxane entities that are currently part of the litigation.<sup>5</sup>

On January 18, 2007, the government filed its notice of intervention and its complaint against the Roxane entities, which was unsealed on January 23, 2007, and the United States served Roxane's counsel with the complaint on February 20, 2007. The claims against Roxane were severed and transferred to the AWP multi-district litigation. The government alleges the submission of false claims submitted to Medicare and Medicaid for the following medications: Azathioprine, Diclofenac Sodium, Furosemide, Hydromorphone, Ipratropium Bromide, Oramorph SR, Roxanol, Roxycodone, and Sodium Polystyrene Sulfonate.<sup>6</sup>

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<sup>5</sup>Roxane Laboratories, Inc. changed its name to Boehringer Ingelheim Roxane, Inc. on April 5, 2005. (U.S. Compl. ¶ 15.)

<sup>6</sup> These drugs treat a variety of conditions as follows: Ipratropium bromide is used to treat respiratory diseases, including chronic bronchitis and asthma; furosemide is used to treat high blood pressure; azathioprine is used to prevent rejection of a kidney transplant and treat severe rheumatoid arthritis; diclofenac is used to treat arthritis; hydromorphone, oramorph, roxanol and roxycodone are high level narcotics used as pain killers; and sodium polystyrene is used to treat high blood potassium. (U.S. Mem. Opp'n Defs.' Mot. Dismiss U.S. Compl. 3 n.4.)

Ven-A-Care moved for leave to amend its complaint by adopting the government's complaint on March 29, 2007, which motion was granted on April 17, 2007. In its motion, Ven-A-Care asserted: "Pursuant to 31 U.S.C. § 3730(c)(1), Ven-A-Care has the right to continue as a party to the action against Roxane and elects to exercise that right."

### **DISCUSSION**

#### **A. Government Complaint**

##### **1. Relation-Back**

Roxane argues that most of the government's claims are untimely because its complaint was filed in 2007, and therefore any alleged false claim prior to 2001 is barred by the FCA's six-year statute of limitations. The government argues that the original filing of the relator's action against Roxane in 2000 tolled the statute of limitations as to the FCA claims asserted by both the relator and the United States, or alternatively that the United States' claims are timely because they relate back to the relator's claims against Roxane. In light of the multiple amendments of the relator's complaint, and the complex history of this case in two jurisdictions, the timeliness of the FCA claims is far from clear-cut.

The FCA allows a private citizen, called a relator, to initiate a qui tam action "in the name of the Government" alleging that the United States has been defrauded in connection

with a federal program. 31 U.S.C. § 3730(b)(1). The government has the right to investigate the allegations and decide whether to intervene and take over the action. Id. § 3730(b)(2). The statute includes provisions that allow the government to apply for extensions "for good cause shown." Id. § 3730(b)(3). There is no statutory cap on the number of extensions the government may seek. During the period in which the government is deciding whether to intervene, the complaint must remain under seal and the relator may not serve the complaint on any defendant. Id. § 3730(b)(2). Once the government intervenes, it has the "primary responsibility for prosecuting the action, and shall not be bound by an act of the person bringing the action." Id. § 3730(c)(1). The relator has the right to continue as a party to the action. Id. The FCA provides a six-year limitations period within which to bring civil actions for false claims. Id. § 3731(b)(1).<sup>7</sup>

The difficult question is how to evaluate the timeliness of the government's complaint filed almost seven years after the relator's complaint. In Baylor, the Second Circuit surprised the

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<sup>7</sup> 31 U.S.C. § 3731(b) provides: "A civil action under section 3730 may not be brought --

(1) more than 6 years after the date on which the violation of section 3729 is committed, or

(2) more than 3 years after the date when facts material to the right of action are known or reasonably should have been known by the official of the United States charged with responsibility to act in the circumstances, but in no event more than 10 years after the date on which the violation is committed,

whichever occurs last."

government and qui tam bar when it disagreed with multiple lower court rulings and held that a government action under the FCA commenced for limitations purposes on the date the government's complaint in intervention was filed in a relator's qui tam suit. Baylor, 469 F.3d at 268. The court held that under Fed. R. Civ. P. 15(c)(2),<sup>8</sup> the government's complaint did not relate back to the relator's qui tam complaint, which was filed under seal, reasoning: "The secrecy required by § 3730(b) is incompatible with Rule 15(c)(2), because (as is well-settled) the touchstone for relation back pursuant to Rule 15(c)(2) is notice, i.e., whether the original pleading gave a party 'adequate notice of the conduct, transaction, or occurrence that forms the basis of the claim or defense.'" Id. at 270 (citations omitted). In the view of the Baylor court, because the seal provision of § 3730(b) deprived the defendant in an FCA suit of notice, relation back was unwarranted under Rule 15(c)(2). Id. Significantly, however, the Second Circuit pointed out that there was a "colorable argument" that Rule 15(c)(1)<sup>9</sup> might be applicable

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<sup>8</sup> Fed. R. Civ. P. 15(c)(2) provides that "[a]n amendment of pleading relates back to the date of the original pleading when . . . the claim or defense asserted in the amended pleading arose out of the conduct, transaction, or occurrence set forth or attempted to be set forth in the original pleading." The language of Fed. R. Civ. P. 15 has been amended, effective December 1, 2007, but these amendments do not affect the analysis.

<sup>9</sup> Under Fed. R. Civ. P. 15(c)(1), "[a]n amendment of a pleading relates back to the date of the original pleading when

because the FCA itself "implicitly 'permit[s]' a form of relation back that dispenses with the requirement of notice." Id. (citations omitted).

The issue of the applicability of Rule 15(c)(1) arose in United States ex rel. Ven-A-Care of the Fla. Keys, Inc. v. Dey, Inc., 498 F. Supp. 2d 389, 396-98 (D. Mass. 2007), where I concluded: (1) that the action commences, for purposes of the statute of limitation, when the relator files its sealed complaint against a defendant and otherwise meets the requirements of 31 U.S.C. § 3730(b); and (2) that the government's complaint in intervention should be treated as an amended complaint that relates back to the relator's complaint under Fed. R. Civ. P. 15(c)(1). However, recognizing that relation-back under Rule 15(c)(1) is limited, I held that if the "government's complaint contains new claims unrelated to those asserted in the original complaint, then the original complaint cannot serve as a proper placeholder under Rule 15(c)(1)." Dey, 498 F. Supp. 2d at 398. However, I did not grapple with the

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... relation back is permitted by the law that provides the statute of limitations applicable to the action." This subsection was added as part of the 1991 amendments to Rule 15. The Advisory Committee Notes state that this provision "is intended to make it clear that the rule does not apply to preclude any relation back that may be permitted under the applicable limitations law...Whatever may be the controlling body of limitations law, if that law affords a more forgiving principle of relation back than the one provided in this rule, it should be available to save the claim." Fed. R. Civ. P. 15 advisory committee's note.

standard for evaluating whether claims against the defendant in the government's complaint are sufficiently related to the claims in the initial complaint to relate back. Id. at 398 n.5.

Two courts have expressly declined to follow Baylor. See United States ex rel. Miller v. Bill Harbert Int'l Const., Inc., No. 95-1231, 2007 WL 851855, at \*2 (D.D.C. March 14, 2007) (holding that relation back under Rule 15(c)(2) applies to FCA Claims); United States ex rel. Parikh v. Premera Blue Cross, No. CV01-0476, 2007 WL 1031724, at \*3-4 (W.D. Wash. Apr. 3, 2007) (finding that the statute of limitations is tolled until the relator's complaint is unsealed).

There is no dispute that the first complaint brought by Ven-A-Care with respect to Ipratropium Bromide in April 2000 is timely under the FCA's six-year statute of limitations. See 31 U.S.C. § 3731(b)(1). There is also no dispute that Ven-A-Care's first and second amended complaints - filed on February 15, 2001 and February 1, 2002, respectively - were timely pled under the FCA's statute of limitations. See Id. The second amended complaint added Roxane's parent corporation, Boehringer Ingelheim, Corporation. In addition, this complaint added allegations that defendants defrauded Medicare (in addition to Medicaid). These subsequent amendments involving Ipratropium Bromide properly relate back to the initial complaint under either Rule 15(c)(1) or 15(c)(2) as each involves the same alleged pricing scheme for the same drug against the same

defendant (and an affiliated entity).<sup>10</sup>

Ven-A-Care's third amended complaint, filed on February 15, 2005, seeks to state a claim involving several new drugs for the first time. The government argues that the relator's third amended complaint should relate back to its first complaint with respect to the new drugs because, under Rule 15(c)(2), the allegations involving new drugs are part of the same "broad scheme of price manipulation" that forms the basis of the earlier complaints. Baylor did not address whether an amendment to the relator's complaint should be evaluated under Rule 15(c)(1) or 15(c)(2). Under either prong of the rule, relation back would be inappropriate. There are insufficient allegations that the circumstances of the pricing for each drug are similar. The conclusory allegation of one "broad scheme" is inadequate particularly in light of the evidence in this MDL demonstrating that each drug must be analyzed differently. Accordingly, with

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<sup>10</sup>Fed. R. Civ. P. 15(c)(3) provides that "[a]n amendment of a pleading relates back to the date of the original pleading when...the amendment changes the party or the naming of the party against whom a claim is asserted if the foregoing provision (2) is satisfied and, within the period provided by Rule 4(m) for service of the summons and complaint, the party to be brought in by amendment (A) has received such notice of the institution of the action that the party will not be prejudiced in maintaining a defense on the merits, and (B) knew or should have known that, but for a mistake concerning the identity of the proper party, the action would have been brought against the party." The standard for relation back with respect to additional related defendants involves determinations that have not been adequately briefed by the parties.

respect to the new drugs, the third amended relator complaint does not relate back to the original relator complaint. Also with respect to these new drugs, the complaint in intervention only relates back to the 2005 Ven-A-Care complaint and all claims that accrued prior to February 15, 1999 are time-barred, unless saved by the discovery rule, as discussed below.

## **2. Discovery Rule**

The government argues that its claims with respect to the additional drugs initially included in Ven-a-Care's third amended complaint are timely pursuant to 31 U.S.C. § 3731(b)(2). 31 U.S.C. § 3731(b)(2) prohibits a civil action under § 3730 from being brought "more than 3 years after the date when facts material to the right of action are known or reasonably should have been known by the official of the United States charged with responsibility to act in the circumstances, but in no event more than 10 years after the date on which the violation is committed." To enjoy the benefits of this tolling provision, the government must act with due diligence in uncovering the fraud. See United States v. Intrados / Int'l Mgmt. Group, 265 F. Supp. 2d 1, 12 (D.D.C. 2002). In fact, if the defendant has not affirmatively concealed the fraud, "a plaintiff is deemed to have sufficient notice of critical facts to set the statute of limitations running if the plaintiff has inquiry notice of the injury and its cause." United States ex rel. Miller v. Bill Harbert Int'l Constr., Inc., 505 F. Supp. 2d 1, 8 (D.D.C. 2007).

After receiving information from Ven-A-Care, the State of

Texas also investigated Roxane and brought suit against Roxane for Medicaid pricing fraud in September 2000. Texas subsequently dismissed its complaint and re-filed its case. Texas filed its first amended petition on July 30, 2003. In its complaint, Texas named Roxane Laboratories, Inc., Boehringer Ingelheim Pharmaceuticals, Inc., Ben Venue Laboratories, Inc. and Boehringer Ingelheim Corporation as defendants. This complaint included, *inter alia*, the following drugs: Azathioprine, Diclofenac Sodium, Furosemide, Hydromorphone, Ipratropium Bromide, Roxicodone and Sodium Polystyrene Sulfonate. Texas reached a settlement with Roxane in 2005. As such, the federal government arguably had notice of the drugs and defendants listed in the State of Texas' first amended complaint by no later than July 30, 2003 and therefore the government may not be entitled to rely on 31 U.S.C. § 3731(b)(2) to preserve its claims with respect to these listed drugs. Given the factual determinations central to this claim, this issue cannot be resolved in the context of a motion to dismiss.

**B. Ven-A-Care's Complaint**

Roxane has also moved to dismiss Ven-A-Care's amended complaint. Remember that Ven-A-Care amended its complaint to adopt whole-hog the government's complaint in intervention. Ven-A-Care insists that, regardless of whether the government's complaint is time-barred, Ven-A-Care's complaint was timely filed.

Ven-A-Care's argument is not supported by the basic structure of the FCA. As the Supreme Court has explained, "[t]he FCA can reasonably be regarded as effecting a partial assignment of the Government's damages claim." Vermont Agency of Natural Res. v. United States ex rel. Stevens, 529 U.S. 765, 773 (2000). The relator in an FCA action does maintain certain rights; for example, before the government may dismiss the action over the objections of the relator, the relator must be notified and given the opportunity for a hearing. 31 U.S.C. § 3730(c)(2)(A). But once the government has intervened, the relator has no separate free-standing FCA cause of action. The nature of the FCA dictates that "there is one claim, the government's." United States ex rel. Barajas v. Northrop Corp., 147 F.3d 905, 910 (9th Cir. 1998).

Moreover, Ven-A-Care, as a relator, cannot separately assert claims for fraud or unjust enrichment on behalf of the government. While the FCA conveys standing on the relator to bring claims pursuant to the FCA, "the FCA does not give relators the right to assert common law claims on behalf of the United States." United States ex rel. Walsh v. Eastman Kodak Co., 98 F. Supp. 2d 141, 149 (D. Mass. 2000). Ven-A-Care lacks standing to pursue these common law claims on behalf of the government. See id. Therefore, Ven-A-Care's common law claims must be dismissed.

#### ORDER

The motions to dismiss [Docket Nos. 14 and 20] are ALLOWED, in part, and DENIED, in part.

S/PATTI B. SARIS  
United States District Judge